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Clinical evaluation of a novel commercial single port in laparoendoscopic single-site surgery

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ABSTRACT

Introduction: Endoscopic total extraperitoneal herniorrhaphy (TEP) has emerged as a recognized surgical method for adult inguinal hernia. To reduce port-site-related morbidity and improve postoperative convalescence, a novel surgical approach known as *laparoendoscopic single-site surgery* (LESS) TEP repair has been developed.
Aim: To compare the clinical efficiency of a novel commercial single port with a homemade single port in TEP groin hernia repair.
Methods: Sixty consecutive patients undergoing LESS TEP repair were enrolled in this trial with 31 in the homemade port group and 29 in the commercial single-port group. Preoperative, intraoperative, and postoperative factors were recorded. The patients were interviewed postoperatively at outpatient clinics.
Results: The demographic data were comparable between the two groups. The median operative time was longer in the homemade port group than in the commercial port group (59.4 vs. 51.4 minutes, respectively, $p = 0.04$). The homemade port group was significantly associated with more port-related malfunctions than the commercial port group (19% vs. 0, respectively, $p = 0.02$). The postoperative results were comparable between the groups in pain scores, analgesic requirements, complications, and postoperative convalescence.
Conclusion: The novel commercial single port studied is associated with less intraoperative malfunctions and improved the procedural efficiency of LESS TEP for groin hernia repair. Thus, a well-designed commercial port will be of significant benefit in overcoming the existing procedural inefficiencies of single-port surgery performed using a homemade port, which requires relatively time-consuming procedures and significant experience of the surgeon.

1. Introduction

Endoscopic total extraperitoneal herniorrhaphy (TEP) has emerged as a recognized surgical method for adult inguinal hernia. The laparoscopic TEP repair was associated with less postoperative pain, a shorter period of sick leave, faster recovery, and less chronic pain, compared with open hernia repair.[1–4] In experienced hands, TEP even showed advantages of lower recurrence rate and higher patient satisfaction over its open counterpart.[2,3]

Increasing efforts are being carried out to further reduce port-site-related morbidity and improve postoperative convalescence. This has led to the development of a novel surgical approach known as *laparoendoscopic single-site surgery* (LESS) TEP repair.[5–8] The LESS TEP repair of inguinal hernia was first reported by Cugura and colleagues in 2008.[8] Although early experiences in LESS TEP repair have demonstrated results comparable with those of multiport TEP repair, LESS TEP was associated with lower procedural efficiency due to single-port creation or instrument clashing.[9–11]

In early studies, a commercialized single port was not commonly available, and therefore, surgery was commonly carried out with a homemade single port or a single incision with several fascial punctures.[8,12] The fascial puncture method may lead to skin maceration, fascial tears, gas leakage, and complications in wound

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healing.[12] The homemade single port may be associated with prolonged operative time, glove tear, gas leakage, and ligature loosening.[13–17] Thus, a durable, flexible, and well-designed single-port platform is essential to improve the procedural efficiency of LESS. To the best of our knowledge, none of the commercially available single-port platforms has been compared in a clinical setting. Here, we designed a prospective study to compare the intraoperative and postoperative parameters, and the costs associated with LESS TEP repair using either a homemade single port or a novel commercialized LagiPort (Lagis, Inc., Taichung, Taiwan).

2. Methods

2.1. Protocol

From June 2012 to March 2013, 60 consecutive adult patients with primary or recurrent inguinal hernias were enrolled in this study. The research protocol was approved by the Ethics Committee of the Buddhist Tzu Chi General Hospital, Taipei, Taiwan. We included only patients in whom primary inguinal hernia required surgical treatment. In addition, only the patients who gave consent to participate were included in this study. Patient who cannot receive general anesthesia and those with a history of previous major lower abdominal surgery or concomitant surgical procedures other than hernia repair were excluded from this study. Depending on patients' preferences, surgery was performed using either the novel single port (LagiPort) or a homemade single port. All the procedures were performed by a single surgeon (Y.C.T.) who is experienced in performing the LESS TEP procedures.[7] The baseline characters of the patients, including demographic data, body mass index [BMI (kg/m^2)], American Society of Anesthesiologists (ASA) risk group, previous abdominal or hernia surgery, and associated comorbidities were prospectively collected. The characteristics of each hernia (unilateral, bilateral, type, or symptoms) were recorded. The intraoperative data including operative time, malfunctions of single port, intraoperative complications, and any problem occurring in the operating room were recorded.

2.2. Operative technique

General anesthesia was administered to all patients. A single-dose injection of cefazolin (1000 mg) was intravenously administered as prophylaxis at the time of induction. Except for patients with a history of lower abdominal or urinary tract surgery, Foley catheter was not inserted in any of the other patients. The mesh used was a polypropylene monofilament mesh. The mesh was attached with laparoscopic takers (ProTack; Covidien, Norwalk, CT, USA) in all patients.

2.3. Homemade single port

A 2-cm subumbilical incision was made and then the preperitoneal space was created with blunt finger dissection. An Alexis wound retractor (X-small; Applied Medical, Rancho Santa Margarita, CA, USA) was positioned through the incision with the internal ring anchored below the arcuate line of the posterior sheath. Then a homemade single-access platform was created as previously described by Tai and colleagues (Fig. 1).[12]

2.4. LagiPort

After a 2-cm subumbilical incision was made, the Lagis wound retractor was placed into the incision with the internal ring anchored below the arcuate line of the posterior sheath (Fig. 2-1). The outer ring was then rolled inward until ultimate retraction was achieved. The retractor attachment ring was attached onto the outer ring of wound retractor (Fig. 2-2). The LagiPort was then attached to the retractor attachment ring with the lever lock engaged (Fig. 2-3 and Fig. 2-4).

2.5. Endoscopic TEP technique

After installation of a homemade or the commercial port (LagiPort), the preperitoneal space was created with blunt dissection. Conventional, noncurved, or flexible laparoscopic instruments were used with both ports. The hernia sac was ligated and divided.

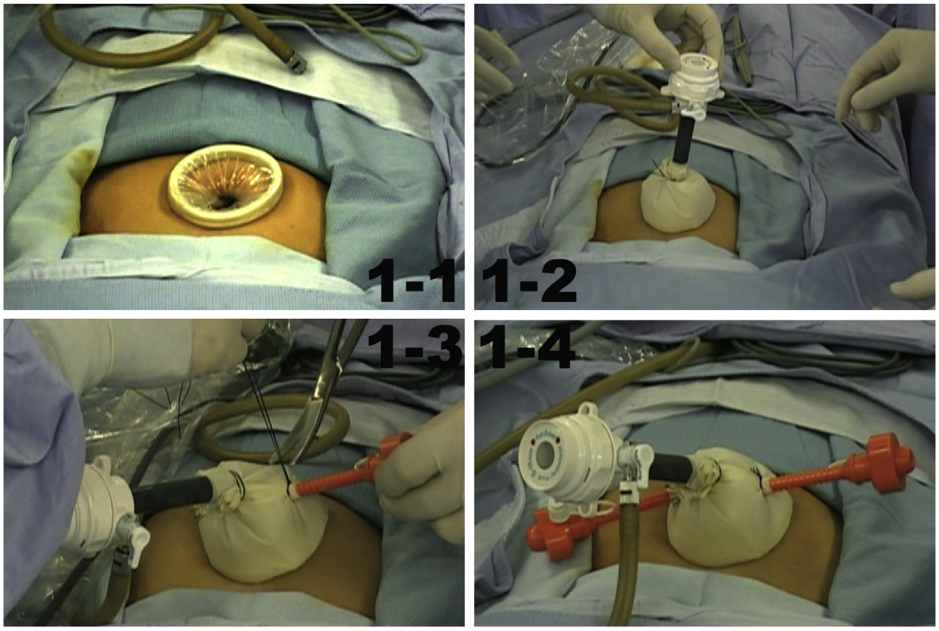

Fig. 1. (1-1) An Alexis wound retractor was placed into the incision. (1-2) A double-layered surgical glove with the finger part trimmed was secured on a 10-mm trocar. (1-3 and 1-4) Another two 5-mm trocars were secured on the homemade port.

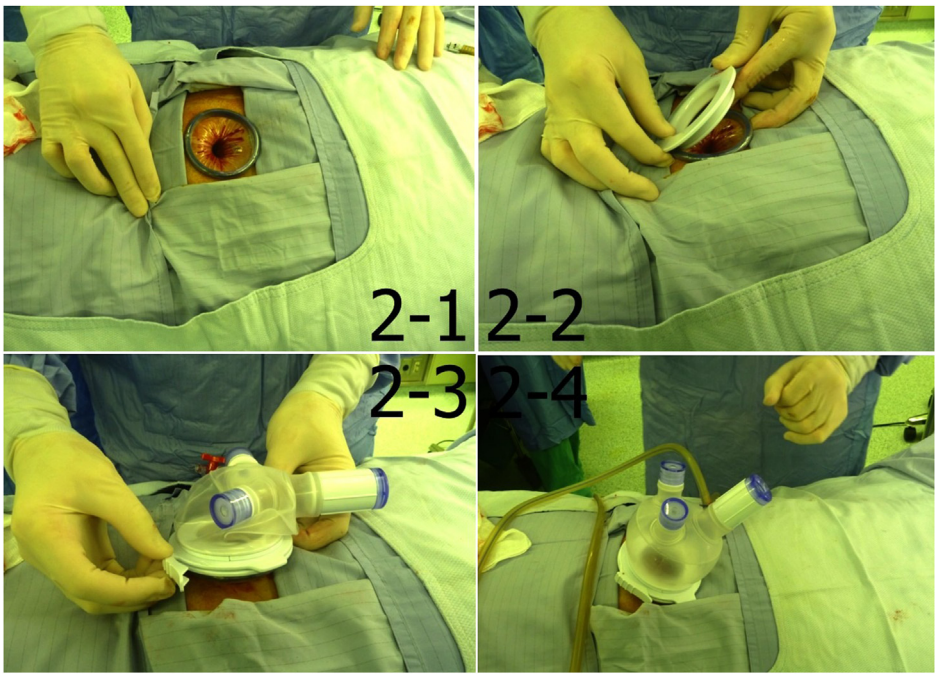

Fig. 2. (2-1) The Lagis wound retractor was placed into the incision. (2-2) The retractor attachment ring was attached onto the outer ring of the wound retractor. (2-3 and 2-4) The LagiPort was then attached to the retractor attachment ring with the lever lock engaged.

The triangle of doom, triangle of pain, and Hesselbach triangle were dissected and identified. After dissection, a 10 × 15-cm^2 polypropylene mesh was introduced through the 11-mm trocar of the homemade or commercial port. The mesh was spread to cover the whole myopectineal orifice and attached with tacks. In bilateral repairs, two pieces of mesh overlapping at the midline were used. The pneumoperitoneum was released. The 10-mm port fascia was closed with 1–0 polyglactin suture and the skin incisions were closed with multiple sutures.

2.6. Postoperative management

After the surgery, all patients were treated in the general ward and started oral intake and ambulation as early as possible. The postoperative pain was managed with on-demand painkillers. The postoperative pain in the inguinal region during resting and coughing was evaluated using a visual analog pain scale 2 and 24 hours after the surgery and at a follow-up visit 7 days later (pain score, 0–10). Patients were discharged after being able to walk, eat, and urinate.

2.7. Follow-up

The patients visited the outpatient clinic after their surgery. The postoperative wound status, hematoma, seroma, complications, and time to return to activity were recorded. The amounts of analgesics required for postoperative pain control after discharge were recorded. Surgical scar lengths were measured on the 7^{th} day of clinic visit.

Summaries of continuous variables were calculated as the mean ± standard deviation. Continuous variables were tested for normality with the Shapiro–Wilk test. The Mann–Whitney *U* test or the independent samples *t* test was used for continuous variables depending on the normality of the variable. For categorized variables, the Fisher exact test and Chi-square test were used. A *p* value less than 0.05 was considered statistically significant. Statistical analyses were performed using SPSS for Windows (version 13.0, SPSS, Inc., Chicago, IL, USA).

3. Results

During the study period, 60 patients were enrolled and divided into the following two groups: the homemade single-port TEP group ($n = 31$) and the commercial single-port TEP group ($n = 29$). The two groups were comparable in age, sex, BMI, smoking history, ASA risk, characteristics of hernia, and clinical symptoms (Table 1).

The median operative time was longer in the homemade port group than in the commercial group (59.4 vs. 51.4 minutes, respectively, $p = 0.04$; Table 2). The homemade single-port group took an average of 8 minutes longer than the commercial single port to complete the repair. There were no major complications, serious wound infections, and intraoperative conversions during the follow-up period. The homemade port was significantly associated with more port-related malfunctions than the commercial single port, and these malfunctions contributed to longer operation times in the homemade port group (19% vs. 0, respectively, $p = 0.02$). There was no significant difference between the two groups in the incidence of postoperative complications ($p = 0.79$).

These two groups were comparable in postoperative pain scores at all periods (Table 3). There were no significant differences between the two groups in the painkiller doses after discharge. Mean duration of postoperative hospital stay was 26.4 ± 12.8 hours with no statistically significant difference between groups. The mean time to return to daily activity was 3.5 ± 0.2 days with no significant difference between groups. There was also no significant difference in the single skin incision length required for a homemade single-port or a commercial port placement. The detailed costs of medical consumables are presented in Table 4. The commercial single-port surgery costs an average US$233 more than the homemade single-port surgery in unilateral hernia repair.

Table 1
Baseline characteristics of patients with inguinal hernia surgically repaired with homemade port LESS TEP or commercial port LESS TEP.

Characteristic	Homemade port LESS TEP	LagiPort LESS TEP	*p*
Number of cases	31	29	
Age, y	48.3 (10.9)	48.2 (14.6)	0.92
Sex			> 0.99
Male	27	25	
Female	4	4	
BMI, kg/m^2	26.4 (10.1)	24.2 (2.3)	0.11
Smoking (%)	3 (9.6%)	7 (24%)	0.17
ASA risk group			0.50
I	13	15	
II	17	14	
III	1	0	
Clinical presentation, no. (%)			0.86
Pain or discomfort	2 (6%)	1 (3%)	
Bulging	3 (10%)	3 (10%)	
Coincidental	26 (84%)	25 (87%)	
Characteristics of hernia, no. (%)			0.47
Left	12 (39%)	7 (24%)	
Right	11 (35%)	13 (45%)	
Bilateral	8 (26%)	9 (31%)	
Type of hernia, no. (%)			NA
Direct	14 (46%)	13 (45%)	
Indirect	15 (48%)	15 (51%)	
Mixed	1 (3%)	0	
Femoral	1 (3%)	1 (3%)	

Data are expressed as mean (standard deviation) or absolute number of patients.
ASA = American Society of Anesthesiologists; BMI = body mass index; LESS = laparoendoscopic single-site surgery; NA = not applicable; TEP = total extraperitoneal herniorrhaphy.

4. Discussion

Despite the increasing applications of LESS in the clinical setting, only rarely have studies been carried out to evaluate the clinical performance of single-access platforms, either homemade or commercially available ones. Although the LESS approach improved cosmetic outcomes, it is inevitably associated with several limitations, such as a single-access platform to maintain the pneumoperitoneum, loss of instrument triangulation, and instrument clashing.[18] Thus, an easy and quick-to-implement single-access platform as the standard laparoscopic trocar system is a basic requirement for performing LESS. To our knowledge, this is the first comparative trial to test a commercially available single port in a clinical setting.

Table 2
Characteristics of intraoperative and postoperative parameters.

Characteristic	Homemade group	LagiPort group	*p*
Operative time, min	59.4	51.4	**0.043**
Median	60	50	
Intraoperative port malfunction			**0.024**
Gas leakage, %	3 (10%)	0	
Port loosening,%	1 (3%)	0	
Trocar ligature loosening, %	2 (6%)	0	
Port breakdown, %	0	0	
Total	6 (19%)	0	
Postoperative complications			
Recurrence	0	0	
Serious wound infection (abscess), %	0	0	
UTI, %	1 (3.2%)	0	
Urinary retention,%	0	0	
Serohematoma, %	2 (6.4%)	2 (6.9%)	
Wound/fascial maceration, %	0	0	
Total number of complications, %	3 (9.6%)	2 (6.9%)	> 0.99

Data are expressed as median or absolute number of patients.
UTI = urinary tract infection.

Table 3
Early postoperative results and postoperative recovery.

Characteristic	Homemade port group	LagiPort group	*p*
Total acetaminophen doses after discharge, mg/kg	23.6 (39.2)	20.2 (27.2)	0.75
Postoperative hospital stay, h	26.5 (12.9)	26.4 (12.9)	0.78
Time to return to daily activity, d	3.4 (1.5)	3.5 (1.7)	0.78
Total length of skin incision, mm	2.4 (0.4)	2.5 (0.3)	0.06
VAS			
2 h (at rest/cough)	3.3 (2.7)/5.4 (2.6)	4.4 (2.5)/6.1 (2.0)	0.07/0.22
24 h (at rest/cough)	1.6 (2.1)/4.1 (2.3)	2.6 (2.1)/4.5 (2.1)	0.06/0.50
7 d (at rest/cough)	0.2 (0.5)/1.1 (1.9)	0.5 (1.5)/1.9 (2.0)	0.29/0.09

Data are expressed as mean (standard deviation) or absolute number of patients.
VAS = visual analog score.

In addition, LESS has been developed in an attempt to reduce the invasiveness and morbidity associated with surgical intervention. Without a functional single port or ergonomically feasible laparoscopic instruments for LESS, unsatisfactory pneumoperitoneal pressure or nonergonomic instruments will impair the procedural efficiency and possibly increase intraoperative complications.[11] Therefore, a comparative study to test existing single-access systems and instruments is essential before these expensive novel devices are widely adopted clinically.

The results of our study revealed that the tested commercialized single-access platform is as safe and feasible as the homemade single port, which had been extensively tested in various urological procedures in our institute.[7,9,11,19–21] The commercial port tested did not experience any malfunction such as gas leakage, port breakdown, and port loosening during the procedure, which sometimes occurred when a homemade port was applied (6/31 vs. 0/29, respectively, $p = 0.024$). The wound protector design of the commercial port retained as excellent a wound protection profile as the Alexis wound protector in the homemade port. Thus, these two groups compared well in postoperative pain, wound-associated complications, on-demand analgesic usage, and convalescence. The 5–5–12-mm configuration of the commercial port also made it easy for surgical mesh and suture needle delivery/removal. Our clinical testing revealed that this novel commercial single port is associated with less intraoperative single-port-related malfunctions than the homemade one.

The mean operative time in the commercial port group is, on average, 8 minutes shorter than that of the homemade port group (51.4 vs. 59.4, respectively, $p = 0.04$). According to our previous experience, the time required to set up a homemade single port is approximately 5–10 minutes.[9,11] To set up a homemade single port,

Table 4
Details of laparoscopic consumables used in homemade single port and commercial single port unilateral TEP repair.

Laparoscopic consumables	Homemade port LESS TEP (no.)	LagiPort LESS TEP (no.)	Cost per piece (US$)
Alexis retractor (X-small)	1	Nil	84
5-mm Trocar	2	Nil	65
12-mm Trocar	1	Nil	53
Optilene mesh (10 × 15 cm^2)	1	1	56
ProTack fixation device	1	1	570
LagiPort kit (5–5–12 mm)	Nil	1	500
Total	893	1126	

LESS = laparoendoscopic single-site surgery; TEP = total extraperitoneal herniorrhaphy.

several complicated steps such as surgical glove design/trimming, glove snapping, and trocar securing ligature are required, all of which are time-consuming (or time-limiting) procedures and require a certain amount of experience. If these steps are not carefully executed, gas leakage and port and trocar loosening may cause problems when performing LESS. In addition, these intraoperative malfunctions of a single port might possibly interrupt or impair the procedure, thereby reducing procedural efficiency compared with the conventional multiport TEP repair. According to our preliminary results, this novel commercial single port could potentially improve the procedural efficiency of an LESS TEP repair.

The only drawback of this novel commercial single port is its cost. For a unilateral LESS TEP repair, the commercial single-port surgery costs an average US$233. The cost-effectiveness of this commercial single port was not evaluated in this study. Thus, a prospective randomized trial to evaluate the cost-effectiveness of such a novel device is vital in the near future.

The limitations of this study are the small number of cases, the short-term follow-up, and the lack of testing in a wide variety of surgical procedures. For an evolving novel technique performed by a single surgeon, recruiting a large cohort is not easy in a limited time.

In conclusion, this novel commercial single port is not only associated with less intraoperative malfunctions but also improved the procedural efficiency of LESS TEP groin hernia repair. Thus, a well-designed commercial port will be of significant benefit in overcoming the existing procedural inefficiencies of single-port surgery performed using a homemade port, which requires relatively time-consuming procedures and significant experience of the surgeon. This commercial single port is highly recommended for beginners who are not familiar with setting up a homemade single port as well as for surgeons inexperienced in performing LESS.

Conflicts of interest

Drs Liu, Chen, and Tsai have no conflicts of interest to disclose.

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